REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

Kindly clarify the status of the pending and rejected claims. In items 4 and 6 on page 1 of the Office Action, it was incorrectly indicated that that claims 1-9, 17 and 18 are pending and rejected. However, please note that claims 1-18 are pending, and claims 1-9, 17 and 18 have been examined on the merits and stand rejected. Although claims 10-16 have been withdrawn, these claims remain pending.

Claim 1 has been amended to incorporate the subject matter of claims 2 and 8. Support can be found in original claims 2 and 8. Additional support for the extracellular matrix language can be found in disclosure, for example, at page 20, lines 4-5.

An editorial revision has been made to claim 3 to use correct punctuation by adding a comma at line 1 between "claim 1" and "further."

An editorial revision has been made to claim 4 to recite "at least one or more kinds" to better conform to US practice and English form. This is a non-substantive change that does not narrow the scope of protection.

Claim 17 has been amended to a "pharmaceutical composition" comprising the cellular preparation of claim 1. Support can be found in the disclosure, for example, at page 1, lines 6-16, page 5, lines 8-20, page 7, lines 10-29 and original claims 10-17.

No new matter has been added.

Claims 2 and 8 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Claims 1, 3-6, 7 and 9-17 are pending upon entry of this amendment.

II. FOREIGN PRIORITY

Kindly acknowledge the claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f), as well as receipt of the certified copies of the foreign priority document.

III. INDEFINITENESS REJECTION

On page 2 of the Office Action, claim 17 was rejected under 35 U.S.C. § 112, second paragraph, for being indefinite on the basis that it is unclear whether the "cellular preparation" is to be used as a medicine, or a "factor" secreted by this cellular preparation is to be used as a medicine.

The present amendment overcomes this rejection as the claim has been amended to a "pharmaceutical composition comprising the cellular preparation of claim 1". It is respectfully submitted that such language is common and well understood in the art. Furthermore, as discussed in the disclosure at page 5, lines 8-20, an object of the present invention is to provide a cellular preparation useful for pharmaceutical compositions for human beings and animals. More specifically, the present invention aims to provide a cellular preparation, wherein cells capable of secreting biologically active factors such as hormones and proteins useful for patients can be retained stably for a prolonged period of time in PVA for treatment purposes. Based on such disclosure and the knowledge in the art, it is respectfully submitted that the skilled artisan would clearly understand the metes and bounds of the claim language a "pharmaceutical composition comprising the cellular preparation of claim 1."

Therefore, the 112, second paragraph, rejection of claim 17 is untenable and should be withdrawn.

IV. ANTICIPATION REJECTIONS

On page 3 of the Action, claims 1-5, 7 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Aung et al. (Transplantation Proceedings, Vol. 27, No.1, pp. 619-21, February 1995).

On pages 3-4, claims 1, 3, 5-7, and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hayashi et al. (Transplantation Proceedings, Vol. 27, No. 6, pp. 3358-3361, December 1995).

To anticipate a claim, a cited prior art reference must teach each and every element of the claimed invention. See M.P.E.P. § 2131.01.

The present amendment overcomes these rejections for independent claim 1 has been amended to incorporate the cell preservatives of dependent claim 8, which was not included in the rejections. Accordingly, the cited references fail to disclose or suggest each and every element of the claimed invention, namely the cell preservatives language added to claim 1. Thus, the cited references cannot anticipate the claimed invention.

Therefore, the 102(b) rejection of claims 1-5, 7 and 18 over Aung et al. and the 102(b) rejection of claims 1, 3, 5-7, and 9 over Hayashi et al. are untenable and should be withdrawn.

V. OBVIOUSNESS REJECTION

On pages 5-7, claims 1, 3-9, and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over Inuoe et al. (Pancreas, Vol. 7, No. 5, pp. 562-568, 1992) and Mitsuo et al. (Transplantation Proceedings, Vol. 24, No. 6, pp. 2939-2940, 1992) in view of Kanazawa et al. (Cell Transplantation, Vol. 8, No. 4, pp. 383-388, Abstract, 1999) and Inui et al. (Pancreas, Vol. 23, No. 4, pp. 382-386, Abstract, 2001).

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. M.P.E.P. § 2143.03. Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. M.P.E.P. § 2143.01. Third, the prior art must provide a reasonable expectation of success. M.P.E.P. § 2143.02.

The present amendment overcomes this rejection for independent claim 1 has been amended to incorporate the essential feature of coating the cells with an extracellular matrix of dependent claim 2, which was not included in the rejection. Accordingly, the cited references fail to disclose or suggest each and every element of the claimed invention. Thus, the cited references cannot render obvious the claimed invention.

In addition, Inuoe et al. disclose a mesh-reinforced polyvinyl alcohol tube (page 562, in the Summary at lines 10-12). Similarly, Mitsuo et al. disclose a mesh-reinforced

polyvinyl alcohol tube (MRPT) (page 2939, left column, lines 9-11). Mitsuo et al. further indicates that MRPT was implanted into the abdominal cavity of the recipient (page 2939, Item of "Islet Isolation and MRPT implantation, lines 4-8).

However, Inuoe et al. and Mitsuo et al. fail to disclose or suggest the cell preservative and extracellular matrix components of the present invention.

Kanazawa et al. disclose University of Wisconsin (UW) solution and Euro-collins solution (page 383, item of AB, lines 15-20). Similarly, Inui et al. disclose University of Wisconsin (UW) solution (page 382, item of AB, line 2).

However, neither reference discloses or suggests the polyvinyl alcohol membrane and extracellular matrix components of the present invention.

Accordingly, in addition to not teaching each and every element of the present invention, the cited references lack a suggestion and reasonable expectation of success to combine and/or modify their teachings to arrive at the claimed invention. For this additional reason, the cited references cannot render obvious the claimed invention.

Thus, the 103(a) rejection of claims 1, 3-9, and 18 over Inuoe et al. and Mitsuo et al. in view of Kanazawa et al. and Inui et al. is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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